1. The enclosed briefing package includes the FDA Guidance document entitled, "Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater". This update of a previous guidance was designed to address issues previously identified by the FDA Transmissible Spongiform Encephalopathies Advisory Committee (i.e., FDA TSE Advisory Committee). In addition, to this guidance, what other types of descriptive information should be included in the classification definition for processed human dura mater?

2. Based on the supplied publication, your knowledge of other scientific and medical literature and current medical practice,

    a. Please discuss the different uses and what issues should be considered for processed human dura mater medical devices? For example, what are the appropriate indications for use for processed human dura mater?

    b. Please discuss what differences if any, might exist in the surgical techniques used to implant processed human dura mater (e.g., suturing place versus a lay-on graft). What surgical technique issues should be considered?

3. Currently the processed human dura mater may be labeled for neurosurgical repair of defects in a patient's dura mater. Based on the supplied publication, your knowledge of the scientific literature and current medical practice, do the data support the use of processed human dura mater in the repair of both cranial and spinal dura mater?

4. For processed human dura maters, Medical Device Reports (MDRs) have identified clinical and technical problems associated with its use as

    - technical – device contamination; and
    - clinical – death, infection, failure.

    a. Based on the supplied publication, your knowledge of other scientific and medical literature and current medical practice, have all the risks to health for processed human dura mater been adequately identified? If not, what are the additional risks that should be described? (see question 3 in the Questionnaire).

b. Have appropriate methods been identified to control each risk to health? For example,

- Donor screening
- Processing controls
- Product labeling
- Training
- Pre-clinical testing
- Other

If not, what are the additional controls needed to control the risks to health?

c. For this device, please discuss the circumstances which may suggest additional clinical data is needed.